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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Chandler et al.

Serial No. 09/662,790

Filed: September 15, 2000

For: CREATION OF A DATABASE OF  
BIOCHEMICAL DATA AND  
METHODS OF USE

Group Art Unit: 1631

Examiner: Clow, L.

Atty. Dkt. No. 5868-02801

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*Pamela Gerik*  
Pamela Gerik

REQUEST FOR PRE-APPEAL BRIEF REVIEW

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

Dear Sir/Madam:

A Notice of Appeal in response to the Final Office Action mailed June 29, 2005 for the captioned case is filed concurrently herewith. The Appellant respectfully requests a review of the presented arguments in accordance with the Pre-Appeal Brief Conference Pilot Program.

REMARKS

Claims 8-38 were canceled. Claim 39 was withdrawn. No claims have been allowed or objected to. Claims 1-7, 40, and 41 stand finally rejected. Claims 1-7, 40, and 41 are the subject of the Notice of Appeal filed in conjunction herewith.

**SECTION 112, SECOND PARAGRAPH, REJECTIONS**

Claims 1-7, 40, and 41 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Errors in the Rejections of Claims 1-7, 40, and 41**

The Examiner's basis for maintaining the rejections of claims 1 and 7 as being indefinite due to the recitation of the term "interact selectively" is improper. The basis for these rejections is improper for the following reasons set forth in more detail on pages 4-6 of the Amendment; Response to Office Action mailed December 28, 2004 filed in the present case by Applicant on March 25, 2005 (hereinafter "the prior response") and on pages 2-3 of the Response After Final Rejection Pursuant to 37 C.F.R. § 1.116 that is filed in the present case concurrently herewith (hereinafter "the present response"):

1. *The Examiner has rejected the claims based on the incorrect assertion that a term known in the art, if not defined in the Specification, renders the claims indefinite.* The term "interact selectively" is known in the art, and the term is not assigned any special meaning in the specification. A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as any special meaning assigned to a term is clearly set forth in the specification. MPEP 2173.01.
2. *The Examiner has analyzed the claim language in a "vacuum."* The term "interact selectively" as recited in the claims is definite when analyzed in light of the content of the present application disclosure, the teachings of the prior art, and the claim interpretation that would be given by one possessing the ordinary skill in the art. Description of the term "interact selectively" can be found in the Specification, for example, on page 4, lines 1-3, page 15, lines 11-17, and page 20, line 24 to page 21, line 2. In addition, examples of patents that illustrate that the term "interact selectively" was known by one possessing ordinary skill in the pertinent art about the time the invention was made are listed on page 5 of the prior response. Based on the description provided in the Specification and the teachings of the prior art, one of ordinary skill in the art would clearly understand the metes and bounds of the present claims.

3. *The Examiner has rejected the claims based on the incorrect assertion that since various prior art references indicate that the term "selectively" can mean a number of things, without clarification of the metes and bounds intended by Applicant, this term is indefinite. Even if the term "interact selectively" can have a number of meanings according to teachings of the prior art, since the term is not assigned a special meaning in the specification, the term "interact selectively" can have any of these known meanings.*
4. *The Examiner has incorrectly equated breadth of a claim term with indefiniteness. Even if a claim term such as "interact selectively" can be broadly interpreted by one of ordinary skill in the art, breadth of claim terminology does not render a claim indefinite. A claim cannot be rejected as indefinite simply because it is broad in scope.*

For at least the reasons set forth above, claims 1 and 7 and claims dependent therefrom (claims 2-6, 40, and 41) have been erroneously rejected under § 112, second paragraph.

#### **SECTION 103 REJECTIONS**

Claims 1-7, 40, and 41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kettman et al. (Cytometry (1998) 33:234-243) (hereinafter "Kettman") in view of Ekins (Journal of Pharmaceutical and Biomedical Analysis (1989) 7: 155-168) (hereinafter "Ekins").

#### **Errors in the Rejections of Claims 1-7, 40, and 41**

The Examiner has failed to establish *prima facie* obviousness of the claimed invention recited in claims 1 and 7. For at least the reasons set forth on pages 7-13 of the prior response, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify Kettman with Ekins or to combine the teachings of Kettman and Ekins. In addition, there is no reasonable expectation of success in the teachings of Kettman and Ekins. Furthermore, the prior art references do not teach or suggest all the claim limitations. Therefore, none of the three basic criteria required to establish a *prima facie* case of obviousness has been met.

The Examiner's basis for maintaining the rejections of claims 1 and 7 fails to establish *prima facie* obviousness of the claimed invention recited in claims 1 and 7. *Prima facie* obviousness of claims 1 and 7 has not been established for the following reasons, which are set forth in more detail on pages 3-7 of the present response:

1. *The Examiner has erroneously relied on Ekins to teach more than 64 sets in analyte analysis.* Sets are defined in Kettman as microsphere sets. However, Ekins does not teach or suggest analyte analysis using microspheres or microsphere sets. Therefore, Ekins does not teach more than 64 "sets" in analyte analysis as asserted in the Final Office Action. As such, this basis for the obviousness rejections of the present claims is improper.
2. *The Examiner has erroneously relied on Ekins to teach that more than 64 sets may be used in analyte analysis, with a reasonable expectation of success.* Ekins teaches that analyzing tens or hundreds of analytes is feasible using a technology that is different than the technology taught by Kettman. Ekins does not teach or suggest that measuring tens or hundreds of analytes is technically feasible using the microsphere sets taught by Kettman or any other microspheres or microsphere sets. As such, Ekins cannot teach or suggest reasonable expectation of success for using more than 64 sets of microspheres for analyzing analytes. As such, this basis for the obviousness rejections of the present claims is improper.
3. *The Examiner has failed to consider the prior art references in their entirety.* The Examiner contends that the manner in which fluorescence, and therefore analyte discrimination, is imparted to the assays of the prior art is irrelevant to establishing a *prima facie* case of obviousness. However, the manner in which fluorescence is imparted to the assays in the prior art must be considered by the Examiner to determine if reasonable expectation of success is taught or suggested by the prior art for "more than 64 sets."
4. *The Examiner has failed to consider the teachings of Kettman in their entirety.* Kettman teaches that applying the technology of Ekins to the technology of Kettman will increase the non-uniformity of the fluorescent characteristics of the microspheres thereby reducing the number of microsphere sets that can be used in the assay. As such, Kettman does not teach or suggest reasonable expectation of success for combining the technology taught by Ekins with the assays of Kettman to produce more than 64 sets that can be used in analyte analysis.

For at least the reasons cited above, none of the prior art teaches or suggests reasonable expectation of success for combining the teachings of Kettman and Ekins as suggested in the Final Office Action. Consequently, the Examiner has failed to establish *prima facie* obviousness of claims 1 and 7 and claims dependent therefrom (claims 2-6, 40, and 41).

### CONCLUSION

For the foregoing reasons, it is submitted that the Examiner's rejections of claims 1-7, 40, and 41 are erroneous, and reversal of the decision is respectfully requested.

Respectfully submitted,



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